V. Analyte Concentration Determination

[0096] Many embodiments of the subject methods also include determining the concentration of at least one analyte in the physiological sample (step 10 of Figure 1). As such, once a suitable sampling site is found and sample is accesses and collected therefrom, the concentration of at least one analyte of the sample may be determined using any appropriate analyte concentration determination method, as are known in the art.

[0097] In certain embodiments of the subject methods, the sample is then transferred to a standard analyte concentration determination reagent test strip, *e.g.*, a glucose test strip or the like, which is in communication with the device, where oftentimes the test strip may be directly integrated into the device. In those embodiments where the test strip is directly integrated into the device, the test strip may be loaded directly into the device before, during or after the physiological sample is extracted, and in many instances may be manufactured with the test strip already integrated with the device.

[0098] Once sample is transferred to a test strip, *i.e.*, delivered to the reaction area of the test strip, the concentration of at least one analyte of interest is determined. Sample may be transferred to a test strip by a variety of mechanisms, where such mechanisms include, but are not limited to, vacuum, capillary forces and the like. As will be apparent to one of skill in the art, a variety of analyte determination methods may be employed, *e.g.*, electrochemical and colorimetric, where both methods will be described below.

[0099] For an electrochemical analyte concentration determination assay, an electrochemical measurement is made using reference and working electrodes, as is known in the art. The electrochemical measurement that is made may vary depending on the particular nature of the assay and the device with which the electrochemical test strip is employed, *e.g.*, depending on whether the assay is coulometric, amperometric or potentiometric. Generally, the electrochemical measurement will measure charge (coulometric), current (amperometric) or potential (potentiometric), usually over a given period of time following sample introduction into the reaction area. Methods for making the above described electrochemical measurement are further described in U.S. Patent Nos. 4,224,125; 4,545,382; and 5,266,179; as well as WO 97/18465; WO 99/49307; the disclosures of which are herein incorporated by reference. Regardless of the type of

measurement, an electrochemical measurement or signal is made in the reaction zone of the test strip.

[00100] Following detection of the electrochemical measurement or signal generated in the reaction zone as described above, the amount of the analyte present in the sample introduced into the reaction zone is then determined by relating the electrochemical signal to the amount of analyte in the sample.

[00101] Generally, for colorimetric assays, the sample is allowed to react with a reagent system, *e.g.*, members of a signal producing system, to produce a detectable product that is present in an amount proportional to the initial amount present in the sample. In one such system, e.g., in a system used to determine the presence and/or concentration of glucose in a physiological sample, the signal producing system is an analyte oxidation signal producing system. By analyte oxidation signal producing system is meant that in generating the detectable signal from which the analyte concentration in the sample is derived, the analyte is oxidized by a suitable enzyme to produce an oxidized form of the analyte and a corresponding or proportional amount of hydrogen peroxide. The hydrogen peroxide is then employed, in turn, to generate the detectable product from one or more indicator compounds, where the amount of detectable product generated by the signal measuring system, *i.e.* the signal, is then related to the amount of analyte in the initial sample. The amount of detectable product, *i.e.*, signal produced by the signal producing system, is then determined and related to the amount of analyte in the initial sample. Of course, any type of colorimetric assay, i.e., various colorimetric chemistries, may be used with the present invention.

[00102] In many embodiments, the above described characterization and relation processes are performed by an automated device, *e.g.*, a meter, as is well known in the relevant art. Representative meters for automatically practicing these steps are further described in copending U.S. Application Serial Nos. 09/333,793; 09/497,304; 09/497,269; 09/736,788 and 09/746,116, and U.S. Patent Nos. 4,734,360; 4,900,666; 4,935,346; 5,059,394; 5,304,468; 5,306,623; 5,418,142; 5,426,032; 5,515,170; 5,526,120; 5,563,042; 5,620,863; 5,753,429; 5,573,452; 5,780,304; 5,789,255; 5,843,691; 5,846,486; 5,968,836 and 5,972,294; the disclosures of which are herein incorporated by reference.

DEVICES

[00103] As summarized above, the invention provides devices for determining a suitable site for sampling physiological fluid, by way of a site flow characterization element and/or a sample type characterization element. The devices may also include at least one skin-piercing element for piercing the skin at the appropriate sampling site and/or include an operatively associated means for determining the presence and/or concentration of at least one analyte in a physiological sample extracted or expressed from the appropriate sampling site. The subject devices find use in the location of suitable physiological fluid sampling sites on various areas of the body, including, but not limited to, the fingers, arms, legs, earlobes, heels, feet, nose and toes. Furthermore, the subject devices find use in the location and collection of a wide variety of physiological samples, where such samples include, but are not limited to, interstitial fluids, blood, blood fractions and constituents thereof, and the like.

[00104] As described above, the subject invention includes at least one site flow characterization element and/or at least one sample type characterization element, where one or both types of the elements may be integrated into a housing or may otherwise be a single unit, *i.e.*, an integrated device, usually with at least one skin piercing element and/or test strip. The unit, *i.e.*, the housing, may be manufactured from a wide variety of materials including, but not limited to, polystyrene, polypropylene, polyethylene, polyacryonitrile, polycarbonate, and the like. The unit may be re-usable or single use.

[00105] The housing is intended to be easily held by the user, *i.e.*, a hand-held device, and as such is sufficiently compact to enable portability and ease-of-use. Accordingly, the housing may take a number of different shapes, as long as the shape enables the functionability of the device, *e.g.*, facilitates portability and grasping by the user and positioning on an appropriate sampling site area, such as a surface area of the skin. For example, the shape may be substantially irregular or may assume a substantially regular shape such as a parallelogram, rhombus, circle, oval and the like. Regardless of the shape, the unit and associated elements typically have a length in the range from about 1 to 20 inches, usually in the range from about 2 to 15 inches and more usually in the range from about 3 to 10 inches. The width of the unit is usually in the range from about 0.1 to 10 inches, usually in the range from about 0.2 to 5 inches and more usually in the range from about 0.5 to 3 inches. The height is usually in the range from about 0.1 to 10